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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/678,357	10/04/2000	Sven Mardh	SMAR.P001	4507
21121 7590 04/28/2005 OPPEDAHL AND LARSON LLP P O BOX 5068 DILLON, CO 80435-5068			EXAMINER HINES, JANA A	
			ART UNIT 1645	PAPER NUMBER
DATE MAILED: 04/28/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/678,357

Applicant(s)

MARDH ET AL

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 15, 18-30 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 15, 18-30 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Amendment Entry

1. The amendment filed November 5, 2004 has been entered. Claim 14 has been amended. Claims 1-13, 16-17, 31 and 33-34 have been cancelled. Claims 14-15, 18-30 and 32 are under consideration in this office action.

Withdrawal of Rejections

2. The rejection of claims 39-43 under 35 U.S.C. 103(a) as being unpatentable over Lindgren et al., has been withdrawn in view of applicants amendments.

Response to Arguments

3. Applicant's arguments filed November 5, 2004 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The rejection of claims 14-15, 18, 30, and 32 under 35 U.S.C. 103(a) as being unpatentable over Oksanen et al., in view of Ma et al., is maintained for reasons already of record. The rejection was on the grounds that it would have been prima facie obvious for a person of ordinary skill in the art to combine the two antibody assay method which diagnosis the presence of gastritis in a human as taught by Oksanen et al., and Ma et al., since no more than routine skill would

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have been required to combine two well known gastritis diagnosis methods to achieve a single method of diagnosis.

Applicants argue that there is no evidence of record that spending more money and effort to perform multiple tests would lead any improvement in results. However, the issue is not whether there is any evidence of record that spending more money leads improvement; rather the issue is whether Oksanen et al., in view of Ma et al., teach the instantly claimed method.

Applicants state that there is no evidence that the references have been previously combined. However, contrary to applicants belief, it is prima facie obvious that the combination of two methods each of which is taught in the prior art to be useful for the same purpose, in order to form a third combination of those methods which would be used for the very same purpose. In this case, the method of Oksanen et al., and Ma et al., teach assaying blood for the presence of antibodies specific for H,K-ATPase, *Helibacter pylori*, and pepsinogen I; comparing the results of the sample to results from normal populations, performing mathematical analysis on the sample results and determining that the different values are indicative of gastritis, atrophic corpus gastritis, chronic gastritis and gastritis without any autoimmunity, just as instantly claimed.

The idea of combining separate compositions useful for the same purpose then flows logically from their having been individually taught in the prior art. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). Thus it is noted that the examiner relies on more than just mere statements as claimed by applicants; rather the Court in *In re Crockett*, 279 F.2d

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274, 126 USPQ 186 (CCPA 1960) observed that claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious. Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron; and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) states that mixture of two known herbicides held prima facie obvious). Thus, the basis for obviousness is not based on the indication of isolated elements as applicants' states. The basis and suggestion and motivation clearly comes from the teaching that it was prima facie obvious at the times of applicants invention to combine two well known methods of diagnosing gastritis in humans as taught by Oksanen et al., and Ma et al., comprising assaying blood for the presence of antibodies specific for H,K-ATPase, *Helibacter pylori*, and pepsinogen I, which is taught in the prior art to be useful for the same purpose of diagnosis gastritis, in order to form a combination of those methods (i.e., the instantly claimed methods) which would be used for the very same purpose of diagnosing gastritis. Therefore, applicants' arguments are not persuasive.

Applicants assert that the there is no support for statements drawn to limitations such as higher or lower levels of indicators or calculating ratios of indicators are being viewed as limitations of optimizing experimental parameters, therefore the rejection should be withdrawn. It is noted that the claims fail to recite an active method step with respect to claims 18-30 and 32, rather the

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claims recite language drawn to determined levels of the antibodies and pepsinogen are indicative of gastritis, thus these claims are merely recitations of the intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). In this case, the methods taught by Oksanen et al., and Ma et al., are capable of producing results which show varying levels of antibodies and pepsinogen and allowing one of ordinary skill in the art to determine what those levels are indicative of since he references teach the comparison of blood test results and the indicative ness of various forms of gastritis.

Moreover, it is noted that generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an

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acid concentration of 10%.); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.") *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable there over because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990).

Therefore, in the instant case, the examiner has provided support as to why the optimization limitations fail to provide a basis for patentably, contrary to applicants' statements. It is also noted that applicant has failed to show that a particular range is critical, or show that the claimed range achieves unexpected results relative to the prior art range. Therefore in view of applicants' failure to claim critical ranges or show unexpected results, the rejection is maintained.

Therefore, contrary to applicants' assertions, the examiner has identified though the art and substantiated the reasons for rejections.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines 
April 25, 2005


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